FDA Approves ENBREL to Induce Major Clinical Response in Patients With Rheumatoid Arthritis; Additional Data Demonstrates Increased Levels of Sustained Disease Control

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THOUSAND OAKS, Calif. & COLLEGEVILLE, Pa.--(BUSINESS WIRE)--Sept. 28, 2004--Enbrel(R) (etanercept) is the first and only biologic to receive an indication by the U.S. Food and Drug Administration (FDA) to induce a Major Clinical Response in patients with rheumatoid arthritis (RA), Amgen Inc. (Nasdaq:AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), announced today. In addition, the FDA approved updated radiographic data in the ENBREL label, which demonstrated that more than half of ENBREL patients observed in an open-label long-term study experienced no progression of joint damage for up to five years.

"Achieving a Major Clinical Response represents a significantly high level of symptom control over a sustained period of time," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development, Amgen. "The impressive treatment response observed with ENBREL should become a new benchmark for patients with RA and their physicians in evaluating the success of therapy."

Major Clinical Response is defined as achieving an American College of Rheumatology 70 response (ACR 70) for six consecutive months. ACR response scores are categorized as ACR 20, ACR 50 and ACR 70 with ACR 70 being the highest level of sign and symptom control in this evaluation system. ACR response scores measure improvement in RA disease activity, including joint swelling and tenderness, pain, level of disability and overall patient and physician assessment.

In addition to the Major Clinical Response indication, the ENBREL label was updated to include data which showed that at five years, patients with early, active RA continued to demonstrate inhibition of joint damage and more than half (55 percent) had no progression of joint damage.

"For patients with RA and their physicians, ENBREL can offer a proven treatment that provides significant and sustained symptom relief. Moreover, ENBREL has demonstrated the ability to halt the progression of joint damage for up to five years for most patients," said Gary L. Stiles, M.D., executive vice president and chief medical officer of Wyeth Pharmaceuticals. "Improving signs and symptoms and halting the progression of joint damage can help a patient's ability to perform activities of daily living."

More than two million Americans have RA, which is a chronic and progressive disease that causes stiffness, swelling and limitation in the motion and function of multiple joints. If RA is left untreated, patients can become disabled from progressive joint damage caused by the disease, limiting their ability to function.

About ENBREL

ENBREL is the only fully human TNF receptor approved to reduce signs and symptoms, induce Major Clinical Response, inhibit the progression of structural damage, and improve the physical function in patients with moderately to severely active RA. ENBREL is also indicated to reduce the signs and symptoms and inhibit the progression of structural damage of active arthritis in patients with psoriatic arthritis. ENBREL is the only biologic therapy approved in the U.S. for first-line treatment of RA patients, and can be used alone or in combination with methotrexate.

ENBREL is approved to reduce the signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis (JRA) in patients who have had an inadequate response to one or more DMARDs. It is also the only biologic approved in the U.S. to treat the signs and symptoms in patients with active ankylosing spondylitis (AS). ENBREL is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

ENBREL has been used by more than 250,000 patients worldwide across indications.

ENBREL acts by binding TNF, one of the dominant inflammatory cytokines or regulatory proteins that play an important role in both normal immune function and the cascade of reactions involved in the inflammatory process of RA, JRA, psoriasis, psoriatic arthritis and AS. The binding of ENBREL to TNF renders the bound TNF biologically inactive, resulting in significant reduction in inflammatory activity.

Since the product was first introduced, the following have been reported in patients using ENBREL:

- Serious infections
  - Many occurred in people prone to infection, such as those with advanced or poorly controlled diabetes
  - Some serious infections were fatal
  - Rare cases of tuberculosis
- What to do/not to do
  - Do not start ENBREL if you have an infection or are allergic to ENBREL or its components.
  - Tell your doctor if you are prone to infection.
  - Stop ENBREL if a serious infection occurs.

- Contact your doctor if you have questions about ENBREL or develop an infection.

- Tell your doctor if you have ever been treated for heart failure.

-- Serious nervous system disorders such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes

- Tell your doctor if you have ever had any of these disorders or if you develop them after starting ENBREL.

-- Rare reports of serious blood disorders (some fatal)

- Contact your doctor immediately if you develop symptoms such as persistent fever, bruising, bleeding, or paleness.

-- In medical studies of all TNF-blockers, a higher rate of lymphoma (a type of cancer) was seen compared to the general population; however, the risk of lymphoma may be up to several fold higher in RA and psoriasis patients.

- The role of TNF-blockers in the development of lymphoma is unknown.

-- The incidence of other cancers has not increased with exposure to ENBREL and is similar to the expected rate.

-- ENBREL can also cause injection site reactions.

-- In a medical study of patients with JRA, infections, headaches, abdominal pain, vomiting, and nausea occurred more frequently than in adults.

- The kinds of infections reported were generally mild and similar to those usually seen in children.

- Other serious adverse reactions were reported rarely, including serious infections (2 percent) and depression/personality disorder (1 percent).

Amgen and Wyeth Pharmaceuticals, a division of Wyeth, market ENBREL in North America. Wyeth markets ENBREL outside of North America. Immunex Corporation, a wholly owned subsidiary of Amgen, manufactures ENBREL. Additional information about ENBREL, including full Prescribing Information, can be found on the Web site sponsored by the companies at www.enbrel.com or by calling toll free 888-4ENBREL (888-436-2735).

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology and vaccines. Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended December 31, 2003, and in Amgen's periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Amgen's results may be affected by its ability to successfully market both newand existing products domestically and internationally, sales growth of recently launched products, difficulties or delays in manufacturing its products, and regulatory developments (domestic or foreign) involving current and future products and manufacturing facilities.

In addition, sales of Amgen's products are affected by reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may

affect the development, usage and pricing of Amgen's products. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify side effects or manufacturing problems with its products after they are on the market.

In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product.

In addition, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third party suppliers.

The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events that involve risks and uncertainties including, without limitation, risks associated with the inherent uncertainty of the timing and success of pharmaceutical research, product development, manufacturing, commercialization, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade buying patterns, wars or terrorist acts, product liability and other types of lawsuits, the impact of legislation and regulatory compliance and obtaining reimbursement, favorable drug pricing, access and other approvals, environmental liabilities, and patent, and other risks and uncertainties, including those detailed from time to time in the Company's periodic reports, including current reports on Form 8-K, quarterly reports on Form 10-Q and the annual report on Form 10-K, filed with the Securities and Exchange Commission. Actual results may vary materially from the forward-looking statements. The Company assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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